

Extracting information from hospital records: what patients think about consent

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Background and objective: There is increasing regulation and concern about the use of material from patients' records. Studies on patients' views have focused on primary care and on use of material for research. This study investigated patients' preferences about whether and how doctors should seek permission for use of specified items of anonymised information from their hospital records for clinical audit, teaching, national data collection and research.

Method: A specially designed questionnaire sent to recently discharged patients under the care of medical and surgical specialists.

Results: 166/316 (53%) patients completed the questionnaires. The percentage of respondents who "definitely wanted" or "preferred" to be asked for permission for use of anonymised information was highest for medical history (21%) and reasons for treatment (20%). The purpose for which information was requested (eg, research, audit) made little difference to the overall percentages (range 10–12%). 21 (13%) patients "definitely wanted" to be asked for permission for use of some item or proposed use of information—most had no preference or preferred not to be asked. The most popular method for asking permission was signing a form while in hospital, rather than by specific requests later.

Conclusions: Most hospital patients have no preference or prefer not to be asked permission for doctors to use information from their records. About 1 in 8 patients would like to be asked for permission, some even for clinical audit of outcomes—although a minority, this could compromise thorough clinical audit. Systems for obtaining permission when patients are admitted to hospital need to be considered. Resolution of uncertainties surrounding legislation on the use of information would be helpful to clinicians.

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There has been increasing debate about the use of stored personal information—both in general and in medical practice. This applies in the UK, North America and other countries.^{1–12} Use of material from patients' healthcare records (medical notes) has become more regulated, and public sensitivity about use of notes has been increasingly recognised.^{2–4 6 9 11–13} In the UK, regulation in this area is becoming more complex: research using medical records has to go through the National Health Service (NHS) research governance process, following which consent will usually be required for a study to proceed.⁴ Audit, on the other hand does not at the moment require explicit individual patient consent. Routinely collected clinical data have also traditionally been used without specific consent in epidemiological studies and they are being used increasingly to publicise the outcomes of individual hospitals.^{14 15}

Studies on the views of patients about the use of information and giving consent have been based largely in primary care and there is little information about patients' views on use of data taken from their hospital records.^{12 16} Importantly, most of the published information has been about the use of information for research and has not explored any other purposes for which information is commonly needed, such as clinical audit, providing guidance for the treatment of others and medical education. Clinical audit has been a particular concern for many clinicians who see review of outcomes and associated data from the records of their patients as part of good clinical practice and beyond the scope of requesting consent (not least because any patients who refuse permission might be those with bad outcomes which particularly need to be reviewed). Little is known about patients' views on the use of different kinds of information held in their records.^{12 17} Lastly, most studies have addressed the use of identifiable or

potentially identifiable information—not information that is anonymised.

We sought the views and preferences of patients recently discharged from hospital on whether they would want to be asked to give permission for doctors to use specific but anonymised information from their notes, for different purposes, and if so—how. We hypothesised that most patients would be willing for information to be used for clinical audit and education without specific consent, and that most of those who wanted to be asked for permission would be content to give this in advance when they attended hospital for inpatient treatment.

METHODS

Questionnaires were sent to 336 adult patients recently discharged from the care of 78 bed-holding consultants across all specialties at the Royal Devon and Exeter Hospital (letters were sent to 82 consultants and positive responses were received from 78). The Royal Devon and Exeter Hospital is a district general and teaching hospital in the southwest of England, serving a population of about 350 000 for all services apart from neurosurgery and cardiac surgery. We selected patients after writing to each consultant and then identifying the patients from the hospital patient administration system. They consisted of the first five patients in alphabetical order, who were admitted under the care of each consultant during the month of July 2004. Consultants were informed about the identities of their five patients to check that there was any special reason why a patient should not be approached.

We sent out the questionnaires once only, during the first half of October 2004 and responses received up to 15 December 2004 were included. Questionnaires were accompanied by a letter from the authors which explained the study and its

purpose, with clear advice and the voluntary nature of participation.

The study and all the documentation received ethics approval from the North and East Devon local research ethics committee.

A questionnaire was developed by a lengthy iterative process, between clinicians and academics with experience in research methods, including questionnaire design and analysis. The variety of issues involved made design of the questionnaire in a readily understandable format difficult. Therefore several questionnaire designs were developed and amended before deciding on the final version. This comprised four pages (including the explanatory text and the tables which patients were asked to mark). When agreed by the researchers, this questionnaire was piloted with six patients (recently discharged patients who had had treatment under the care of the senior author, BC), and amendments were made in the light of their comments.

The questions are shown in the legends in tables 1–3 in the Results section. The first section of the questionnaire invited participants to state their preferences about whether they would want to be asked permission for specific pieces of information to be used from their hospital records (for example age, gender, diagnosis, treatment). Another section sought to understand whether the need for permission altered depending on the purpose for which the information was to be used (for example clinical audit, education, research). The final section invited patients to state how they would prefer to give permission (four options). The questionnaire specified that only those who had stated that they wanted to be asked for permission in the two preceding questions should answer this section. Throughout the questionnaire the phrase “give permission” was used rather than “consent” because we felt it conveyed the meaning of the questions more clearly: for the

purposes of this report the two phrases should be considered as equivalent. Similarly, although this study is using the term “hospital records” the questionnaire used the phrase “hospital notes” as the pilot study of the questionnaire showed that this was how patients referred to their records.

Note that the questionnaire stated clearly that requests would be for doctors only to use material from records, and that all material would be used anonymously.

Data are presented as raw figures with percentages. Statistical tests were not used.

RESULTS

Of the 336 patients to whom questionnaires were sent, 17 had died and three refused to participate. Of the remaining 316, 166 (53%) completed and returned the questionnaire. Table 1 shows their preferences for being asked permission for various different pieces of information to be extracted from their hospital records. The greatest proportions of patients wanted to be asked for permission when their medical history (21%) or the reason for their treatment (20%) was required. The smallest proportions wanted to be asked permission when their age (7%) or gender (5%) was required. With regard to sexual orientation, 14% wanted to be asked.

The purpose for which the information was required had little influence on patients' preferences: nearly a third had no preference or view. Only 10% wanted to be asked if information was to be used for clinical audit. Similarly, about 10% preferred to be asked (only two definitely wanted to be asked) for permission when information was intended to help future patients or to teach healthcare professionals. The purpose for which the highest percentage (12%) wanted or preferred to be asked permission was publication of information in medical journals.

Table 1 Responses to the question: “If a doctor wanted to take any of the following pieces of information from your notes, which ones would you prefer to give your permission for?”

	No response	(A) I would definitely want to be asked for permission	(B) I would prefer to be asked for permission	(C) I have no preference or view	(D) I would prefer not to be asked for permission	(E) I would definitely not want to be asked for permission	Proportion who definitely wanted or who preferred to be asked
Your age	3	2 (1)	9 (6)	54 (33)	20 (12)	78 (48)	11/163 (7)
Your gender (male/female)	3	2 (1)	6 (4)	55 (34)	20 (12)	80 (49)	8/163 (5)
Your social class (not recorded in your notes but “guessed” from your postcode)	8	10 (6)	11 (7)	46 (29)	27 (17)	64 (41)	21/158 (13)
Your ethnicity (race)	4	3 (2)	9 (6)	57 (35)	24 (15)	69 (43)	12/162 (7)
Your sexual orientation	6	8 (5)	14 (9)	48 (30)	24 (15)	66 (41)	22/160 (14)
The reason that you have had your treatment	5	9 (6)	24 (15)	45 (28)	22 (14)	61 (38)	33/161 (20)
Your medical history (other illnesses or operations)	5	9 (6)	25 (16)	45 (28)	21 (13)	61 (38)	34/161 (21)
Other things that may impact on your health (your smoking habit and alcohol consumption)	5	6 (4)	13 (8)	55 (34)	23 (14)	64 (40)	19/161 (12)
The type of treatment you had	4	6 (4)	16 (10)	53 (33)	22 (14)	65 (40)	22/162 (14)
Any side effects (complications) of your treatment	4	6 (4)	20 (12)	52 (32)	20 (12)	64 (40)	26/162 (16)
Whether your treatment was medically successful	3	5 (3)	21 (13)	51 (31)	19 (12)	67 (41)	26/163 (16)

Percentages are shown in parentheses, to the nearest integer: the denominator was the total number of responses.

Table 2 Responses to: "This section is about the possible reasons why doctors might want to take information and what they might use it for. Please indicate which of these reasons you would prefer to give your permission for by marking X in one box for each"

	No response	(A) I would definitely want to be asked for permission	(B) I would prefer to be asked for permission	(C) I have no preference or view	(D) I would prefer not to be asked for permission	(E) I would definitely not want to be asked for permission	Proportion who definitely wanted or who preferred to be asked
To allow doctors to monitor their work by reviewing the results of their treatment of patients	5	1 (1)	15 (9)	48 (30)	25 (17)	72 (45)	16/161 (10)
To be used with other patient data to provide better information for future patients	6	4 (3)	13 (8)	49 (31)	26 (16)	68 (43)	17/160 (11)
To share information about how a treatment is working with other healthcare professionals in the hospital	6	2 (1)	14 (9)	46 (29)	25 (16)	73 (46)	16/160 (10)
To provide better information for the teaching of healthcare professionals	6	2 (1)	14 (9)	47 (29)	25 (16)	72 (45)	16/160 (10)
To produce national figures which are published to let the public know about the results of different hospitals	6	7 (4)	10 (6)	53 (33)	26 (16)	64 (39)	17/160 (11)
To publish information about diseases and treatments in medical journals	6	5 (3)	14 (9)	47 (29)	27 (17)	67 (42)	19/160 (12)

Percentages are shown in parentheses, to the nearest integer: the denominator was the total number of responses.

Only 21 (13%) patients "definitely wanted" to be asked permission for the use of any information from their notes, in response to any part of the questionnaire. Specifically, 18 individuals said that they would "definitely want to be asked for permission" for one or more items of material specified in table 1 to be used. Nine individuals said that they would "definitely want to be asked for permission" for material to be used for one or more of the purposes specified

in table 2. Six of these respondents were the same in the two tables.

Table 3 shows choices of patients for various ways of being asked for permission. Although only those who had expressed a preference to be asked for permission in the two preceding questions should have responded to this section, some who had not done so offered responses (and a small number made more than one choice). These were included. As shown in table 3 the

Table 3 Responses to: "This section asks how you would like to give your permission. Please mark X in one of the four boxes to describe how you would like to give permission for each of the pieces of information. Only do this for information where you marked column A or B above (in other words, only for those items for which you would prefer to be asked for your permission)."

	No response Not applicable	(A) Signing a form when you are in hospital giving permission for material from your notes to be used in the future	(B) Being sent a form to sign each time doctors want to use material from your hospital notes	(C) Being telephoned to ask for permission each time doctors want to use material from your hospital notes	(D) Being informed each time material is being used (but not being asked for your permission)
Age	89 2	48 (66)	1 (1)	3 (4)	21 (29)
Gender	89 2	48 (67)	1 (1)	1 (1)	22 (30)
Social class	82 2	48 (61)	9 (11)	3 (4)	19 (24)
Ethnicity	85 2	49 (64)	3 (4)	3 (4)	22 (29)
Sexual orientation	81 2	49 (61)	6 (8)	5 (6)	20 (25)
Reason for treatment	80 2	49 (60)	10 (4)	3 (12)	20 (24)
Medical history	79 2	47 (57)	14 (17)	3 (4)	19 (23)
Alcohol/smoking	86 3	45 (60)	9 (12)	1 (1)	20 (27)
Type of treatment	85 2	45 (58)	8 (10)	3 (4)	21 (27)
Side effects	83 2	44 (56)	10 (13)	3 (4)	22 (28)
Whether successful	83 2	45 (57)	10 (13)	2 (3)	22 (28)

Seventy-one patients should have answered these questions based on their previous responses.

Percentages are shown in parentheses, to the nearest integer: the denominator was the total number of responses.

most popular choice was "Signing a form when you are in hospital giving permission for material to be used in the future", followed by "Being informed each time material is being used (but not being asked for your permission)". Only small numbers of patients chose the other two options.

DISCUSSION

In the UK, confidentiality and use of material in healthcare records is governed by a variety of laws, namely the Data Protection Act 1998, the Human Rights Act 1998, the Health and Social Care Act 2001 and the common law of confidentiality. However, there has been considerable uncertainty, among clinicians and regulatory bodies alike, about the precise implications of these pieces of legislation with a tendency towards restriction and conservatism in permitting use of personal data without consent. In fact, these laws allow for the use of anonymous data and they also permit identifiable data to be used without consent provided that such use is necessary and any infringement of privacy is proportionate to the public interest and benefits of such use. The Patient Information Advisory Group has been established to advise on whether identifiable data may be used for particular research ventures.¹⁸ These issues are described in detail in document published recently (since the completion of this study) by the Academy of Medical Sciences.⁴

Elsewhere in the world also, uncertainties exist about the interpretation and use of legislation governing confidentiality and consent for access to material in healthcare records. In the USA, a Minnesota law and a Federal Privacy Rule are both open to varying interpretations.^{5,6} Researchers have examined national legislation and/or reported patients' attitudes to use of material from their records in other countries, including Australia,⁷ Canada,^{3,8,9} Israel,¹⁰ Japan¹¹ and New Zealand.¹²

Most of the tensions relate to identifiable data, particularly when they are to be used by third parties. In general, there seems to be acceptance that data used by clinical teams responsible for a patient's care are reasonable and permissible, although the cultural and legal shifts towards data protection have caused some clinicians concern about using material for any purpose other than that for which the patient imparted it—that is to aid their clinical care. When used by anyone other than the clinical team, the general principle is "consent or anonymisation". However, anonymisation of data strictly needs to be effected before researchers or others have access to records and can reduce the value for research if important data items are removed (for example postcode of residence).

Before any discussion of our results and their implications, the response rate of only 53% to this survey needs to be considered. We had aimed to investigate the views of a substantial number and wide range of patients, in contrast with other studies that have interrogated smaller numbers of patients (although their aims were rather different, focusing on exploration of the underlying issues, rather than quantifying them).^{2,3,9,13} In this study, we sent the questionnaire only once, and, we argue, the response rate we achieved is broadly comparable with other studies using a similar method. We acknowledge that selecting patients, as we did, using alphabetic order, may run the risk, in diverse communities, of over, or under, representing some ethnic groups. Our study was undertaken in a district general hospital serving a community which consists of less than 2% non-white communities, so we feel that this did not markedly affect our results.

We chose to specify that material would be used by doctors (rather than other clinical staff) so that there would be no uncertainty—either on the part of the patients responding to the question or on the part of those considering our findings—about who would have access to their records for the purposes

of this enquiry. In practice different clinical staff and others might extract information, but we wanted to present patients with a well-defined scenario.

The overall results show that most of the respondents had either no preference about having their permission sought, or preferred not to be asked. Only a minority responded that they would want to be asked before any material from their hospital records was used. Interestingly, the 13% who definitely wanted to be asked for permission is a similar percentage to the 9.8% reported by Baker *et al* as the percentage of patients who refused permission for use of their primary care records in a study of implementation of guidelines for asthma and angina (requests sent to 5069 patients).¹⁹

In a study from Canada, Willison *et al* reported that most of their patients were willing to allow anonymised material from their electronic records from primary care to be used for research purposes, but most wanted to be asked for permission first.³ In that study, patients expressed particular concerns about their data being used for research funded by drug companies or sponsored by central government. With this in mind, an unexpected finding of the present study was the lack of differences in preferences depending on the purpose for which the information was to be used. We had anticipated that more preferences would be expressed for permission to be asked if the material was required for research purposes than when it was required "to allow doctors to monitor their work by reviewing the results of their treatment of patients" or "to be used with other patient data to provide better information for future patients". Many doctors may be dismayed that approximately 1 in 10 patients would like to be asked for permission for material from their records to be used for clinical audit purposes. Using material from patients' records for clinical audit is regarded by most clinicians as beyond dispute—not least because the capacity of patients to refuse could mean that bad outcomes might escape thorough review. Review of records for personal and local audit of outcomes is both an expectation and requirement for good clinical practice, and we believe it falls outside the boundaries of any ethical demand for patient consent, as indeed obtaining material for research purposes sometimes might.^{20,21} The potential for patients to refuse consent to anonymous data being used for national figures on treatments and outcomes is also a matter for concern.²² A previous study has shown a detrimental effect of an explicit "opt in" consent process for inclusion of paediatric patients in a national clinical audit database.²³ However, a recent survey in the UK showed that the great majority of patients considered the use of personal, identifiable information by the National Cancer Registry for the purposes of public health research and surveillance not to be an invasion of privacy.²⁴

The reasons for which patients prefer to be asked permission for use of material from their records are likely to be diverse and were not addressed by this study. It seems possible that uncertainty about who might gain access to personal information plays a part: this was the reason we specified "doctors" in this study. Some patients misunderstand the existing and normal usage of their healthcare records—for example, Carman and Britten found that patients were unaware that administrative staff had access to material in their primary care records.¹³ Such misunderstandings may influence the views of some people who are sensitive about use of their records. Another influence may be the pervasive concern about the amount and use of personal information which is held electronically,¹⁸ perhaps because of fears that this might be accessed by external agencies.² Our questionnaire did not specify whether information was electronic or paper based. Although most of the specified items are stored electronically,

material would in practice be obtained by doctors for the purposes described using paper records, because these are still generally more comprehensive, detailed and reliable in our healthcare system.

The questionnaire suggested a variety of ways of asking for permission to use material from patients' records and the most popular was "Signing a form while in hospital to give permission for future use of material from your notes". This could be part of the hospital admission contract, giving patients a feeling of autonomy over use of their hospital records and also conferring explicit responsibilities on the hospital. To work efficiently and transparently, such a solution may require a degree of public education, explaining to patients why and how such information might be used, including being used to help other patients.

This study shows the diverse views of patients about use of material from their records. It should perhaps stimulate more debate about routinely seeking permission for specified uses of material when patients are admitted to hospital, making clear the differences between identifiable and anonymised data. It would be helpful for more explicit guidance to be available to clinicians about the implications of their national legislation and the degree of latitude which is usually acceptable in their use of data from healthcare records of their patients. Current uncertainties can discourage worthwhile enquiry and research.¹⁻⁴

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